February 22, 2010

Dear Colleague:

Small Business Outreach

This communication is part of our outreach to small businesses in response to Presidential Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking.” In accordance with the principles set forth in this Executive Order, we want to provide you with the opportunity for meaningful and timely input in the development of regulatory policies that may have substantial direct effects on you.

The Food and Drug Administration (FDA) has adopted this process to enhance small entities' input by sending notice of the publication of the *Regulatory Plan (Plan) and Unified Agenda of Federal Regulations (Agenda)*. With this notice and the information we provide on locating the *Plan and Agenda* on the Internet, we send a list of those regulatory items that we believe will be of particular interest to you.

Executive Order 13272 promotes compliance with the Regulatory Flexibility Act which requires Federal agencies to examine the impact of regulations on small entities. As part of this analysis, an agency is required to determine whether or not a rule will have "a significant economic impact on a substantial number of small entities." In the *Agenda*, there is a section where agencies can indicate whether or not a regulatory flexibility analysis is needed. If the agency has either not made that determination yet or has determined that no analysis is required, it may still indicate that some impact on small entities is likely by indicating that in the “Small Entities Affected” section. Please note that the list that we have enclosed with this letter includes both those regulations for which FDA has determined that a regulatory flexibility analysis is required and those for which some impact is likely or “undetermined,” but which may not require a full analysis.

For your information, under section 610(c) of the Regulatory Flexibility Act, Federal agencies are required to review regulations that have or will have a “significant economic impact on a substantial number of small entities” within 10 years of publication in the Federal Register. The purpose of this review is to determine whether the rule should continue without change, be amended or rescinded to minimize the impact on small entities. To comply with this requirement, FDA has implemented the process of identifying these rules to be

reviewed under section 610(c) in the *Agenda*. At this time, FDA does not have any regulations for which 610(c) reviews are being conducted.

Information for You on the Unified Agenda of Federal Regulations (Agenda)

The *Plan and Agenda* provide, among other things, abstracts of all proposed and final regulations currently planned by the FDA for the next six to twelve months, as well as abstracts of planned long-term actions and completed actions. Each entry also contains an indication as to whether or not small businesses may be affected. The *Agenda* is published in the Federal Register twice a year (usually in April and October), with the Fall edition also containing the *Regulatory Plan*. Below is a listing of 41 rulemakings in the Agenda that we believe may impact small entities, and a listing of 26 rulemakings with an "Undetermined" impact on small entities.

We encourage you to review these abstracts and to provide any comments or raise any questions you may have with the contact person listed, or you may contact Mr. Joseph Reardon of the FDA's Division of Federal-State Relations at 301-827-9508, or me.

The *Agenda and the Plan* for the Food and Drug Administration for Fall 2009 published in the Federal Register on December 7, 2009 (74 FR 64424). Please note that the complete *Agenda* is only available online at Regulations.gov. Only rulemakings that are likely to have a significant economic impact on a substantial number of small entities appear in the printed version in the Federal Register.

To access Regulations.gov:

a) Go to Internet site Regulations.gov
b) In the middle of the page, on the right hand side, click on "Regulatory Agenda and Agency Resources."
c) Scroll down to "Regulations.gov Resources," and click on "Regulatory Agenda."
d) Make sure that at "Select Publication Date" that "Fall 2009" is displayed.
e) Under "Select Agency," scroll down to "Department of Health and Human Services," and click "Go."
f) Scroll through to see FDA's portion and to see a specific entry, click on the RIN in blue.

Suggestions Are Welcome

We welcome suggestions and other comments from you on FDA's activities to enhance your input in the development of FDA's regulations, especially those regulations that have a substantial and direct effect on you. Again, you may

send your comments and suggestions to the contact person listed for a particular Federal Register document or by contacting Mr. Joseph Reardon of the FDA's Division of Federal-State Relations or to me.

In addition, we would like to take this opportunity to tell you about FDA's web site for small businesses. It can be found at Small Business Assistance. This site provides information on FDA Small Business contacts, how to participate in various FDA forums, and provides guidance on how to get assistance from the agency.

Sincerely,

Edwin V. Dutra, Jr.
Director, Regulations Policy and Management Staff
Office of Policy, Planning, and Budget
5600 Fishers Lane (HF-26)
Parklawn Building Room 12-A-11
Rockville, MD 20857

Phone: 301-827-3480
Fax: 301-827-1696
e-mail: edwin.dutra@fda.hhs.gov

Enclosures: Lists of 41 Rulemakings Identified by FDA with an Impact on Small Entities, and 26 Rulemakings Identified by FDA with "Undetermined" Impact on Small Entities. All of which can be found in the Unified Agenda which published in the Federal Register on December 7, 2009.

FDA IDENTIFIED RULEMAKINGS WITH IMPACT
ON SMALL ENTITIES

Rulemakings with Impact on Small Entities

1. "Electronic Submission of Data from Studies Evaluating Human Drugs and Biologics," RIN 0910-AC52 (Regulatory Plan)

2. "Produce Safety Regulation," RIN 0910-AG35 (Regulatory Plan)

3. "Modernization of the Current Food Good Manufacturing Practices Regulations," RIN 0910-AG36 (Regulatory Plan)

4. "Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors," RIN 0910-AF27 (Regulatory Plan)

5. "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," RIN 0910-AG33 (Regulatory Plan)

6. "Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures," RIN 0910-AG14

7. "Over-the-Counter (OTC) Human Drugs; Labeling Requirements," RIN 0910-AG34

8. "Electronic Submission of Data from Studies Evaluating Human Drugs and Biologics," RIN 0910-AC52

9. " OTC Drug Review; Cough/Cold (Antihistamine) Products," RIN 0910-AF31

10. "OTC Drug Review; Laxative Drug Products," RIN 0910-AF38

11. "OTC Drug Review; Sunscreen Products," RIN 0910-AF43

12. "OTC Drug Review; Vaginal Contraceptive Products," RIN 0910-AF44

13. "OTC Drug Review; Weight Control Products," RIN 0910-AF45

14. "OTC Drug Review: Poison Treatment Drug Products," RIN 0910-AF68

15. "Process Controls for Animal Feed Ingredients and Mixed Animal Feed," RIN 0910-AG10

16. “Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for OTC Human Use; Proposed Amendment to the Final Monograph,” RIN 0910-AG12

17. “Postmarketing Safety Reporting Requirements for Human Drug and Biological Products,” RIN 0910-AA97

18. “Medical Gas Containers and Closures; Current Good Manufacturing Practices,” RIN 0910-AC53

19. “Positron Emission Tomography Drugs; Current Goo Manufacturing Practices,” RIN 0910-AC55

20. “Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling,” RIN 0910-AF11

21. “OTC Drug Review; Cough/Cold (Bronchodilator) Products,” RIN 0910-AF32

22. “OTC Drug Review; Cough/Cold (Combination) Products,” RIN 0910-AF33

23. “OTC Drug Review; Cough/Cold (Nasal Decongestant) Products,” RIN 0910-AF34

24. “OTC Drug Review; External Analgesic Products,” RIN 0910-AF35

25. “OTC Drug Review; Internal Analgesic Products,” RIN 0910-AF36

26. “OTC Drug Review; Labeling of Drug Products for OTC Human Use,” RIN 0910-AF37

27. “OTC Drug Review; Skin Protectant Products,” RIN 0910-AF42

28. “Use of Materials Derived from Cattle in Human Food and Cosmetics,” RIN 0910-AF47

29. “OTC Drug Review; Acne Drug Products Containing Benzoyl Peroxide,” RIN 0910-AG00

30. "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements," RIN 0910-AB88

31. “OTC Drug Review; Ophthalmic Products,” RIN 0910-AF39

32. “OTC Drug Review; Oral Health Care Products,” RIN 0910-AF40

33. “OTC Drug Review; Overindulgence in Food and Drink Products,” RIN 0910-AF51

34. “OTC Drug Review; Antacid Products,” RIN 0910-AF52

35. “OTC Drug Review; Skin Bleaching Products,” RIN 0910-AF53

36. “OTC Drug Review; Stimulant Drug Products,” RIN 0910-AF56

37. “Label Requirement for Food that has been Refused Admission into the United States,” RIN 0910-AF61

38. “OTC Antidiarrheal Drug Products,” RIN 0910-AF63

39. “OTC Drug Review: Topical Antimicrobial Drug Products,” RIN 0910-AF69

40. “OTC Drug Review: Urinary Analgesic Drug Products,” RIN 0910-AF70

41. “Status of Certain Additional OTC Drug Category II Active Ingredients,” RIN 0910-AF95

<u>FDA Identified Rulemakings With “Undetermined” Impact On Small Entities</u>

1. “Medical Device Reporting; Electronic Submission Requirements,” RIN 0910-AF86 (Regulatory Plan)

2. “Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs held for Retail Distribution,” RIN 0910-AG06

3. “Reporting Information Regarding Falsification of Data,” RIN 0910-AC59

4. “Postmarket Safety Reporting for Combination Products,” RIN 0910-AF82

5. “Laser Products; Amendment to Performance Standard,” RIN 0910-AF87

6. “Electronic Registration and Listing for Devices,” RIN 0910-AF88

7. “Proposed Revisions To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes,” RIN 0910-AF97

8. “Conditional Approval of New Animal Drugs for Minor Use and Minor Species,” RIN 0910-AG07

9. “Pet Food Labeling Requirements,” RIN 0910-AG09

10. “Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products,” RIN 0910-AG18

11. “Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals,” RIN 0910-AG20

12. “Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets; Implementation of Section 505(q) of the Federal Food, Drug and Cosmetic Act,” RIN 0910-AG26

13. “Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner,” RIN 0910-AG27

14. “Informed Consent Elements,” RIN 0910-AG32

15. “Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, including Drugs that are Regulated under a Biologics License Application, and Animal Drugs,” RIN 0910-AA49

16. “Medical Devices; Anesthesiology Devices; Reclassification of Pressure Regulators for Use with Medical Oxygen and Separate Classification of Oxygen Conserving Devices,” RIN 0910-AC30

17. “Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements,” RIN 0910-AF96

18. “Premarketing Safety Reporting Requirements for Human Drug and Biological Products,” RIN 0910-AG13

19. “Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,” RIN 0910-AC50

20. "Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; Revision of Certain Labeling Controls," RIN 0910-AF08

21. "Food Labeling; Prominence of Calories," RIN 0910-AF22

22. "Food Labeling; Serving Sizes of Products that can Reasonably be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes," RIN 0910-AF23

23. "Blood Initiative: Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use," RIN 0910-AF25

24. "Current Good Manufacturing Practice for Combination Products," RIN 0910-AF81

25. "Sunlamp Products; Proposed Amendment to the Performance Standard," RIN 0910-AG30

26. "Unique Device Identification," RIN 0910-AG31

*Abstracts of these planned rulemakings appear in the *Regulatory Plan and Unified Agenda of Federal Regulations*. The *Plan and Agenda* published in the Federal Register on December 7, 2009 and at Regulations.gov (see letter for instructions).